SANDWICHED RADIOPAQUE MARKER ON COVERED STENT

Application No. 10/600,022 Amendment dated February 8, 2011

Reply to Office Action of November 8, 2010

REMARKS/ARGUMENTS

Applicant has carefully reviewed and considered the Office Action mailed on November 8, 2010, and the references cited therewith.

Claims 1, 20, and 32-33 are amended, claims 37-39 are canceled, claims 21-31 are withdrawn, and no claims are added; as a result, claims 1-36 are now pending in this application.

Examiner Interview Summary

Applicant thanks Examiner Ganesan for the courtesy of a telephone interview conducted on January 31, 2011. The independent claims were discussed in view of the cited references and Applicant believes the discussion was helpful in moving the claims toward allowance. However, no specific agreement was reached. Applicant thanks Examiner Ganesan for her time and consideration.

§ 112 Rejection of the Claims

Claims 1-20 and 32-36 were rejected under 35 USC § 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicant respectfully traverses the rejection as follows.

Applicant has amended independent claims 1, 20, and 32-33 to overcome the § 112 rejection thereof. Applicant has amended independent claims 1, 20, and 32-33 to clarify that there is "at least one radiopaque marker of a first set that is directly and only attached to the plurality of interconnected struts at the generally linear connector strut and disposed between the inner covering and the outer covering". That is, Applicant respectfully submits that the amended claim language clarifies that radiopaque markers from the first set are directly and only attached to the plurality of interconnected struts at the generally linear connector strut. Applicant respectfully submits that such a limitation thereby limits the locations on the interconnected struts at which the radiopaque markers can be attached to the linear connector strut, irrespective of to what other structure (e.g., the inner and outer

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coverings) to which the linear connector strut may or may not be interpreted to be attached.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the § 112 rejection of independent claims 1, 20, and 32-33, as currently amended, as well as those claims that dependent therefrom.

§103 Rejection of the Claims

Claims 1-6, 8-11, 15-17, 20, and 32-36 were rejected under 35 USC § 103(a) as being allegedly unpatentable over Wijay (U.S. Patent No. 6,340,366) in view of Cottone, Jr. (U.S. Patent No. 5,824,043) and Ventura (U.S. Publication No. 2004/0044399), with supporting evidence from Edwin, et al. (U.S. Publication No. 2002/0095205) and Wolinsky (U.S. Patent No. 6,331,189). Applicant respectfully traverses the rejection as follows.

Applicant does not admit that the either the Ventura reference or the Edwin reference is indeed prior art and reserves the right to swear behind at a future date. Nonetheless, in the interest of advancing prosecution of the claims of the present application, Applicant respectfully submits that the claims are patentably distinguishable from the teachings of the reference cited in the present FOA for at least the following reasons.

Applicant notes that the Wijay reference appears to teach a "stent with nested or overlapping rings". (Title). The Cottone reference appears to teach an "endoprosthesis having graft member and exposed welded end junctions". (Title). The Ventura reference appears to teach, "radiopaque links for self-expanding stents". (Title). The Edwin reference appears to teach, "encapsulated radiopaque markers". (Title). Applicant further notes that the Wolinsky reference appears to teach a "flexible medical stent". (Title).

However, following review of the Wijay, Cottone, Ventura, Edwin, and Wolinsky references, Applicant respectfully submits that the references, individually or in combination, do not teach, suggest, or render obvious a stent including a single

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tubular framework having an outer surface and an inner surface and a plurality of interconnected struts, the struts including a plurality of serpentine bands and further including a generally linear connector strut attaching a peak of one serpentine band to a trough of an immediately adjacent serpentine band at the respective apices of each of the peak and the trough, where the respective apices of the immediately adjacent serpentine bands are axially aligned and connected with each other in opposing directions such that the single tubular framework has no gaps between the respective apices of the immediately adjacent serpentine bands, and where the opposing apices reduce a distance between the immediately adjacent serpentine bands and attach to the generally linear connector strut, the framework further including an outer covering of PTFE and an inner covering of PTFE, the outer covering extending along at least a portion of the outer surface of the expandable framework, the inner covering extending along at least a portion of the inner surface of the expandable framework, at least a portion of the inner and outer coverings being contiguous, the stent further including at least one radiopaque marker of a first set that is directly and only attached to the plurality of interconnected struts at the generally linear connector strut and disposed between the inner covering and the outer covering, the framework further including a circumferential non-serpentine band at at least one end of the framework including at least one radiopaque marker of a second set, wherein a comparison of the first set and the second set defines an orientation of the inner and outer covering of the PTFE in relation to the at least one end of the framework.

In contrast, Applicant's independent claim 1, as currently amended, presently recites:

A stent comprising a single tubular framework having an outer surface and an inner surface and a plurality of interconnected struts, the struts comprising a plurality of serpentine bands and further comprising a generally linear connector strut attaching a peak of one serpentine band to a trough of an immediately adjacent serpentine band at the respective apices of each of the peak and the trough, wherein the respective apices of the immediately adjacent serpentine bands are axially aligned and connected with each other in

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> opposing directions such that the single tubular framework has no gaps between the respective apices of the immediately adjacent serpentine bands, and wherein the opposing apices reduce a distance between the immediately adjacent serpentine bands and attach to the generally linear connector strut, the framework further comprising an outer covering of PTFE and an inner covering of PTFE, the outer covering extending along at least a portion of the outer surface of the expandable framework, the inner covering extending along at least a portion of the inner surface of the expandable framework, at least a portion of the inner and outer coverings being contiguous, the stent further comprising at least one radiopaque marker of a first set that is directly and only attached to the plurality of interconnected struts at the generally linear connector strut and disposed between the inner covering and the outer covering, the framework further comprising a circumferential non-serpentine band at at least one end of the framework comprising at least one radiopaque marker of a second set, wherein a comparison of the first set and the second set defines an orientation of the inner and outer covering of the PTFE in relation to the at least one end of the framework.

> > Independent claim 20, as currently amended, presently recites:

A stent comprising a single tubular framework having an outer surface and an inner surface and a plurality of interconnected struts, the struts comprising a plurality of serpentine bands and further comprising a generally linear connector strut attaching a peak of one serpentine band to a trough of an immediately adjacent serpentine band at the respective apices of each of the peak and the trough, wherein the respective apices of the immediately adjacent serpentine bands are axially aligned and connected with each other in opposing directions such that the single tubular framework has no gaps between the respective apices of the immediately adjacent serpentine bands, and wherein the opposing apices reduce a distance between the immediately adjacent serpentine bands and attach to the generally linear connector strut, the framework further comprising an outer covering of PTFE and an inner covering of PTFE, the outer cover extending along at least a portion of the outer surface of the framework, at least a portion of the inner and outer coverings being contiguous, the generally linear connector strut having at least one marker of a first set which is radiopaque or which may be visualized using magnetic resonance imaging, the marker of the first set directly and only attached to the plurality of interconnected struts at the generally linear connector strut and disposed between the inner coverings and the outer coverings, the framework further comprising

a circumferential non-serpentine band at at least one end of the framework comprising at least one radiopaque marker of a second set, wherein a comparison of the first set and the second set defines an orientation of the inner and outer covering of the PTFE in relation to the at least one end of the framework.

Independent claim 32, as currently amended, presently recites in part:

at least one radiopaque marker located within the first marker region of said framework, the marker directly and only attached to the plurality of serpentine bands at the generally linear connector strut;

a circumferential non-serpentine band at at least one end of the framework comprising at least one radiopaque marker of a second marker region; and

a covering of expanded PTFE covering the interior surface and exterior surface of said framework in the first marker region; wherein a **comparison** of the first marker region and the

second marker region defines an orientation of the inner and outer covering of PTFE in relation to the at least one end of the framework.

In addition, independent claim 33, as currently amended, presently recites:

A stent comprising a single tubular expandable framework having an outer surface and an inner surface, the tubular expandable framework comprising a plurality of serpentine bands, immediately adjacent serpentine bands having axially aligned and connected oppositely pointing apices such that the single tubular framework has no gaps between the respective apices of the immediately adjacent serpentine bands, wherein the oppositely pointing apices reduce a distance between the immediately adjacent serpentine bands, said framework further including linear connecting members connecting at least some of said oppositely pointing apices of the immediately adjacent serpentine bands, an outer covering of PTFE and an inner covering of PTFE, the outer covering extending along at least a portion of the outer surface of the expandable framework, the inner covering extending along at least a portion of the inner surface of the expandable framework, at least a portion of the inner and outer coverings being contiguous, the stent further comprising at least one radiopaque marker of a first set that is directly and only attached to the plurality of serpentine bands at the generally linear connecting members and disposed between the inner covering and the outer covering, the framework further comprising a circumferential nonserpentine band at at least one end of the framework comprising

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at least one radiopaque marker of a second set, wherein a comparison of the first set and the second set defines an orientation of the inner and outer covering of the PTFE in relation to the at least one end of the framework.

As such, Applicant respectfully submits that the Wijay, Cottone, Ventura, Edwin, and Wolinsky references, individually or in combination, do not teach, suggest, or render obvious each and every element and limitation of Applicant's independent claims 1, 20, and 32-33, as currently amended. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the § 103 rejection of independent claims 1, 20, and 32-33, as currently amended, as well as those claims that depend therefrom.

Claims 7, 12-14, and 18-19 were rejected under 35 USC § 103(a) as being allegedly unpatentable over Wijay in view of Cottone and Ventura, as applied above, further in view of Edwin. Applicant respectfully traverses the rejection as follows.

Claims 7, 12-14, and 18-19 depend directly or indirectly from independent claim 1. As present above, Applicant respectfully submits that independent claim 1, as currently amended, is in condition for allowance in view of the deficiencies of the Wijay, Cottone, Ventura, and Edwin references. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the § 103 rejection of dependent claims 7, 12-14, and 18-19.

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CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's below listed attorney at (612) 236-0126 to facilitate prosecution of this matter.

CERTIFICATE UNDER 37 CFR §1.8: The undersigned hereby certifies that this correspondence is being electronically filed with the United States Patent and Trademark Office on this
Teornary 2011.
J
Argela Miller
A. Miller

Respectfully Submitted, Brent C. Gerberding, et al.

By Applicants' Representatives, Brooks, Cameron & Huebsch, PLLC 1221 Nicollet Avenue, Suite 500 Minneapolis, MN 55403

By: Kevin G. Waddick Reg. No. 57,007

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